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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,381	07/02/2001	Douglas C. Stahl	2703.2	1421
5514	7590	10/06/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/895,381	STAHL, DOUGLAS C.
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 June 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3,5-13,15,17-25,27,29-37,39 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3,5-13,15,17-25,27,29-37,39 and 41-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Applicants' arguments, filed 18 June 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 3, 5-13, 15, 17-25, 27, 29-37, 39, and 41-48 are currently pending.

Claim Rejections - 35 USC § 101

Rejections under 35 USC 101 have been withdrawn in view of Applicant's response and amendments to the claims.

Claim Rejections – 35 USC § 112, 1st Paragraph-Enablement

Rejections under 35 USC 112, 1st paragraph from the **Previous Office Action** have been withdrawn in view of Applicant's response and amendments to the claims. In view of Applicant's amendments, however, **new rejections** under 112, 1st paragraph now apply.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-13, 15, 17-25, 27, 29-37, 39, and 41-48 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying and classifying genotype data obtained from the amplification of nucleic acids in order to identify alleles, does not reasonably provide enablement for a method of identifying and classifying data

(alleles) obtained from **any** analysis of nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to identify and classify nucleic acid data by performing gel electrophoresis, executing frequency transformations, and identifying alleles from background signals. For the reasons discussed below, this constitutes undue experimentation.

b) and c) The specification provides examples for **amplifying** alleles that exist in specific microsatellite marker locations of interest (page 13, lines 32-34). The polymorphic markers are selected for determining a **genotype**. Subsequently, a pair of PCR primers is designed to amplify the alleles of each marker (page 14, lines 3-18). After amplification, gel electrophoresis is performed for the separation of labeled PCR products. The gel is then scanned and converted to a digital image from which additional processing can occur, such as transformation of signals from spatial domain to frequency domain (page 15, lines 5-30).

However, the instant **claims** are drawn to **any** method of analysis of any nucleic acid that would not necessarily lead to the identification of alleles.

d) The invention is drawn to methods of identifying and classifying nucleic acid data by performing gel electrophoresis, executing frequency transformations, and identifying alleles from background signals.

e) It would have been well known in the art that alleles may be determined after amplification of desired genotypic markers by PCR. For example, US 6,100,030 (McCasky Feazel et al.) teach a methods of genotyping mixtures of DNAs, nucleic acids markers etc (see abstract). In the method, a fingerprint is created via the amplification of DNA (column 8, lines 9-26). In general, markers are used to develop a unique fingerprint of genetic polymorphisms. One of skill in the art generates sets of marker nucleic acids for detection of polymorphic nucleotides at specific loci (column 8, lines 51-67). In particular, an AFLP method is used to identify differentially amplified nucleic acid bands on an acrylamide gel.

f) The skill of those in the art of molecular biology is high.

g) The prior art indicates that alleles may be identified through the PCR amplification of genetic markers (see above).

h) The claims are broad because they are drawn to identifying and classifying data (alleles) obtained by any analysis of nucleic acids. The skilled practitioner would first turn to the instant specification for guidance to practice this method. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that such analysis requires the amplification via PCR to identify alleles. Finally, said practitioner would

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turn to trial and error experimentation to determine whether any other DNA analyses would lead one to the identification and classification of alleles. Such represents undue experimentation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 30, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
10/11/04